

Neuada State Board of Pharmacy

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August 1, 2019

NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will hold a Public Hearing at 9:00 a.m. on Thursday, September 5, 2019, at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada. The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to Chapters 453 and/or 639 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B.060:

Amendment of Nevada Administrative Code (NAC) 639.250: Restrictions on supervision. The proposed amendment to NAC 639.250 will allow for an increase in pharmaceutical technician to pharmacist ratio in certain pharmacy settings. (LCB File No. R002-19)

1. The need for and the purpose of the proposed regulation or amendment.

The proposed amendment will authorize a pharmacist to supervise not more than a total of eight pharmaceutical technicians or six pharmaceutical technicians and two pharmaceutical technicians in training at one time in any non-dispensing pharmacy.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

- 3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:
 - (a) Both adverse and beneficial effects.

There should be no adverse economic impact from this regulation amendment on the public.

(b) Both immediate and long-term effects.

The Board anticipates that there will be no immediate or long-term economic effect on the public, or that any such effects will be negligible.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this regulation amendment.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation amendment overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation amendments of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation amendment does not provide a new or increase of fees.

Amendment of Nevada Administrative Code (NAC) 453.520: Schedule II. The proposed amendment will add FDA approved dronabinol oral solution to the controlled substances listed in Schedule II. (LCB File No. R001-19)

1. The need for and the purpose of the proposed regulation or amendment.

The proposed amendment adds such drug products to the list of controlled substances in schedule II in conformity with federal regulations of the Uniform Controlled Substances Act.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

- 3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:
 - (a) Both adverse and beneficial effects.

There should be no adverse economic impact from this regulation amendment on the public.

(b) Both immediate and long-term effects.

The Board anticipates that there will be no immediate or long-term economic effect on the public, or that any such effects will be negligible.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this regulation amendment.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation amendment overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation amendments of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation amendment does not provide a new or increase of fees.

Amendment of Nevada Administrative Code (NAC) 639.NEW LANGUAGE Costs for inspection. The proposed amendment authorizes the Board of Pharmacy to require certain payments from applicants for a certificate, license or permit issued by the Board. (LCB File No. R005-19)

1. The need for and the purpose of the proposed regulation or amendment.

This amendment authorizes the Board to require an applicant for a certificate, license or permit, including, without limitation, a person who holds a certificate, license or permit in another jurisdiction, to pay any costs of inspection incurred by the Board.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

- 3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:
 - (a) Both adverse and beneficial effects.

There should be no adverse economic impact from this regulation amendment on the public.

(b) Both immediate and long-term effects.

The Board anticipates that there will be no immediate or long-term economic effect on the public, or that any such effects will be negligible.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this regulation.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

In addition to any other fees paid by an applicant, for a certificate, license or permit, the regulation amendment will have an economic impact on an applicant for a certificate, license or permit, including, without limitation, a person who holds a certificate, license or permit in another jurisdiction, to pay any costs of inspection incurred by the Board.

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments in written form to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521, or at e-mail address: shunting@pharmacy.nv.gov. Written submissions must be received by the Board at

<u>least fourteen days</u> before the scheduled public hearing. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

A copy of this notice and the regulation to be adopted and amended will be on file at the State Library, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation to be adopted and amended will be available in all counties in which an office of the agency is not maintained, at the main public library, for inspection and copying by members of the public during business hours. The text of each regulation will include the entire text of any section of the Nevada Administrative Code which is proposed for amendment or repeal. This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request. A reasonable fee may be charged for copies if it is deemed necessary.

Upon adoption of any regulation, the agency, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice of hearing has been posted at the following locations:

Nevada State Board of Pharmacy Nevada State Board of Pharmacy

Reno, Nevada Las Vegas, Nevada

Mineral County Courthouse Elko County Courthouse Hawthorne, Nevada Elko, Nevada

Washoe County Courthouse Reno, Nevada

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R002-19

July 12, 2019

EXPLANATION - Matter in *italies* is new, matter in brackets [omitted-material] is material to be omitted.

AUTHORITY: §§1 and 2, NRS 639.070 and 639.1371.

A REGULATION relating to pharmacy; revising provisions concerning the supervision by a pharmacist of pharmaceutical technicians and pharmaceutical technicians in training; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations relating to the practice of pharmacy in this State. (NRS 639.070)

Existing law provides that a pharmaceutical technician is a person who: (1) performs technical services in a pharmacy under the direct supervision of a pharmacist; and (2) is registered with the Board. (NRS 639.0113) Existing law provides that the ratio of pharmaceutical technicians to pharmacists must not allow more than one pharmaceutical technician to each pharmacist unless the Board expands this ratio by regulation. Existing law requires the Board to adopt regulations concerning pharmaceutical technicians, including requirements for the supervision of pharmaceutical technicians. If such regulations prescribe an expanded ratio of pharmaceutical technicians to pharmacists, existing law requires such regulations to be appropriate and necessary for a particular category of pharmacy at any time. (NRS 639.1371)

Existing regulations authorize a pharmacist to supervise more than one pharmaceutical technician in a hospital, in certain pharmacies and in any telepharmacy, remote site or satellite consultation site. (NAC 639.250) In a pharmacy that does not dispense, section 1 of this regulation authorizes a pharmacist to supervise not more than: (1) eight pharmaceutical technicians; or (2) six pharmaceutical technicians and two pharmaceutical technicians in training. Section 2 of this regulation makes a conforming change.

Section 1. NAC 639.250 is hereby amended to read as follows:

639.250 Except as otherwise provided in NAC 639.258:

- 1. Except as otherwise provided in **[this-section,]** subsection 5, in a hospital, a pharmacist who is dispensing prescriptions may not supervise more than a total of three pharmaceutical technicians at one time. A pharmacist who is supervising distributive functions may not supervise more than a total of two pharmaceutical technicians and one pharmaceutical technician in training while the trainee is performing technician functions in on-the-job training.
- 2. Except as otherwise provided in **[this section,]** subsection 5, in any pharmacy, other than a hospital pharmacy, telepharmacy, remote site, satellite consultation site or nondispensing pharmacy, a pharmacist may not supervise more than a total of three pharmaceutical technicians or one pharmaceutical technician and two pharmaceutical technicians in training at one time.
- 3. In any telepharmacy, remote site or satellite consultation site, a pharmacist may not supervise more than a total of three pharmaceutical technicians at one time.
- 4. In any nondispensing pharmacy, a pharmacist may not supervise more than a total of eight pharmaceutical technicians or six pharmaceutical technicians and two pharmaceutical technicians in training at one time.
- 5. A pharmacist may supervise more pharmaceutical technicians and pharmaceutical technicians in training at one time than are otherwise allowed pursuant to subsections 1 and 2 if:
- (a) Not more than three of the pharmaceutical technicians or pharmaceutical technicians in training are performing the duties of a pharmaceutical technician as set forth in NAC 639.245; and

- (b) The record kept by the pharmacy pursuant to NAC 639.245 identifies the pharmaceutical technicians and pharmaceutical technicians in training who are performing the duties of a pharmaceutical technician as set forth in NAC 639.245.
- 6. As used in this section, "nondispensing pharmacy" means a pharmacy that is licensed pursuant to this chapter and chapter 639 of NRS that does not dispense, including, without limitation, drugs, controlled substances, poisons, medicines or chemicals.
 - Sec. 2. NAC 639.258 is hereby amended to read as follows:
- 639.258 1. A pharmaceutical technician in training who is registered with the Board may perform the duties of a pharmaceutical technician while he or she is participating in a program of training for pharmaceutical technicians that is approved by the Board pursuant to NAC 639.256. The registration of such a pharmaceutical technician in training:
 - (a) Will specify the program of training in which he or she is participating; and
 - (b) Expires when the enrollment of the pharmaceutical technician in the program terminates.
- 2. A person who is participating in a program of training for pharmaceutical technicians that is approved by the Board pursuant to NAC 639.256 may be trained in more than one pharmacy as a part of the program.
- 3. A pharmacist who is acting as an instructor for a program of training for pharmaceutical technicians that is approved by the Board pursuant to NAC 639.256 may, while acting as an instructor, supervise one pharmaceutical technician in training, in addition to the persons that he or she may supervise pursuant to *subsection 1, 2, 3 or 5 of* NAC 639.250, if the additional pharmaceutical technician in training:

- (a) Has completed at least 9 months of a program of training for pharmaceutical technicians that is approved by the Board pursuant to NAC 639.256; and
 - (b) Has not yet successfully completed 240 hours of practical training.
- 4. A pharmacist shall not supervise an additional pharmaceutical technician in training pursuant to subsection 3 after that pharmaceutical technician in training has successfully completed 240 hours of practical training.

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R001-19

June 14, 2019

EXPLANATION - Matter in italies is new; matter in brackets [omitted material] is material to be omitted.

AUTHORITY: §1, NRS 453.146 and 639.070.

A REGULATION relating to controlled substances; adding certain substances to the controlled substances listed in schedule II; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations to add, delete or reschedule substances listed as controlled substances in schedules I, II, III, IV and V of the Uniform Controlled Substances Act. (NRS 453.146) Existing law also provides that if a substance is designated, rescheduled or deleted as a controlled substance pursuant to federal law, the Board is required, with certain limited exceptions, to similarly treat the substance under the Uniform Controlled Substances Act. (NRS 453.2182) The Drug Enforcement Administration of the United States Department of Justice has added dronabinol in an oral solution in a drug product approved for marketing by the United States Food and Drug Administration to the list of controlled substances in schedule II of the federal Controlled Substances Act. (21 C.F.R. § 1308.12) This regulation brings the treatment of dronabinol oral solution in a drug product into conformity with federal regulations by adding dronabinol oral solution in a drug product, approved by the United States Food and Drug Administration, to the list of controlled substances in schedule II of the Uniform Controlled Substances Act.

Section 1. NAC 453.520 is hereby amended to read as follows:

453.520 1. Schedule II consists of the drugs listed in this section, by whatever official, common, usual, chemical or trade name designated.

2. Unless specifically excepted or unless listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis, is hereby enumerated in schedule II:

(a) Opium and opiate, and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone and naltrexone, and their respective salts, but including:

Codeine;
Diprenorphine;
Ethylmorphine;
Etorphine hydrochloride;
Granulated opium;
Hydrocodone;
Hydrocodone combination product (meaning any product that contains hydrocodone in
combination with any other active ingredient);
Hydromorphone;
Metopon;
Morphine;
Opium extracts;
Opium fluid;
Powdered opium;

Raw opium;

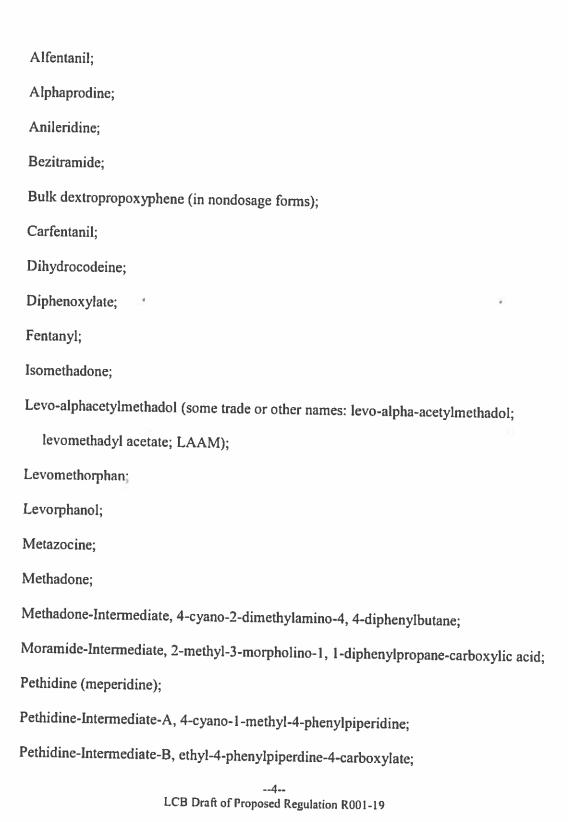
Oxycodone;

Oxymorphone;

Thebaine; and

Tincture of opium.

- (b) Any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (a) if they do not include the isoquinoline alkaloids of opium.
 - (c) Opium poppy and poppy straw.
- (d) Cocaine hydrochloride salt prepared by a registered chemical or pharmaceutical manufacturer of the Drug Enforcement Administration of the Department of Justice which is properly labeled, including lot numbers, and is available for medicinal purposes through a distribution system approved by the Drug Enforcement Administration.
 - (e) Benzolyecgonine or ecgonine.
- (f) Concentrate of poppy straw (meaning the crude extract of poppy straw in either liquid, solid or powder form and containing the phenanthrene alkaloids of the opium poppy).
- 3. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (dextrorphan and levopropoxyphene excepted), are hereby enumerated on schedule II:



Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
Phenazocine;
Piminodine;
Racemethorphan;
Racemorphan;
Ramifentanil;
Sufentanil; or
Tapentadol.

- 4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system is hereby enumerated on schedule II:
 - (a) Amphetamine, its salts, optical isomers and salts of optical isomers;
 - (b) Phenmetrazine and its salts;
- (c) Unless specifically excepted, any preparation which contains any quantity of methamphetamine, including its salts, isomers and salts of isomers, prepared by a registered chemical or pharmaceutical manufacturer of the Drug Enforcement Administration of the Department of Justice, which is properly labeled, including lot numbers, and is available for medicinal purposes through a distribution system approved by the Drug Enforcement Administration;
 - (d) Methylphenidate; or
 - (e) Lisdexamfetamine.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation, is hereby enumerated on schedule II: Amobarbital; Glutethimide; Pentobarbital; or Secobarbital. 6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances is hereby enumerated on schedule II: (a) Immediate precursors to phencyclidine (PCP): 1-Phenylcyclohexylamine; or 1-piperidinocyclohexanecarbonitrile (PCC).

(b) Immediate precursors to amphetamine and methamphetamine:

Phenylacetone (some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone).

- 7. Any material, compound, mixture or preparation which contains any quantity of Nabilone (commonly referred to as: (+)-trans-3-(1,1-dimethylheptyl)-6, 6a, 7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H- dibenzol[b,d]pyran-9-one) is hereby enumerated on schedule II.
- 8. Dronabinol oral solution in a drug product approved by the United States Food and Drug Administration (some trade or other names: (6aR,10aR)-6a,7,8,10a-Tetrahydro-6,6,9-trimethyl-3-penthyl-6H-dibenzo[b,d]-pyran-1-ol; (-)-delta-9-trans-tetrahydrocannabinol; Syndros) is hereby enumerated on schedule II.

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R005-19

June 18, 2019

EXPLANATION - Matter in italies is new; matter in brackets [omitted material] is material to be omitted.

AUTHORITY: §1, NRS 639.070 and 639.170.

A REGULATION relating to pharmacy; authorizing the State Board of Pharmacy to require certain payments from applicants for a certificate, license or permit issued by the Board; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations appertaining to the practice of pharmacy and authorizes the Board to charge and collect fees for the provision of certain services, including, without limitation, providing various licenses and registrations. (NRS 639.070, 639.170) This regulation authorizes the State Board of Pharmacy to require an applicant for a certificate, license or permit, including, without limitation, a person who holds a certificate, license or permit in another jurisdiction, to pay any costs of inspection incurred by the Board.

Section 1. NAC 639.220 is hereby amended to read as follows:

639.220 1. The Board hereby adopts the following schedule of fees:

For the examination of an applicant for registration as a pharmacist Actual cost

of the

examination

For the investigation or registration of an applicant as a registered
pharmacist\$180
For the investigation, examination or registration of an applicant as a
registered pharmacist by reciprocity180
For the investigation or issuance of an original license to conduct a retail
pharmacy500
For the biennial renewal of a license to conduct a retail pharmacy500
For the investigation or issuance of an original license to conduct an
institutional pharmacy500
For the biennial renewal of a license to conduct an institutional pharmacy500
For the investigation or issuance of an original license to conduct a
pharmacy in a correctional institution500
For the biennial renewal of a license to conduct a pharmacy in a
correctional institution
For the issuance of an original or duplicate certificate of registration as a
registered pharmacist50
For the biennial renewal of registration as a registered pharmacist
For the reinstatement of a lapsed registration (in addition to the fees for
renewal for the period of lapse)100
For the initial registration of a pharmaceutical technician or
pharmaceutical technician in training

For the biennial renewal of registration of a pharmaceutical technician or
pharmaceutical technician in training4
For the investigation or registration of an intern pharmacist4
For the biennial renewal of registration as an intern pharmacist40
For the investigation or registration of an advanced practice registered
nurse or a physician assistant to prescribe drugs that are not controlled
substances80
For the biennial renewal of registration of an advanced practice registered
nurse or a physician assistant to prescribe drugs that are not controlled
substances80
For authorization of a physician, advanced practice registered nurse,
physician assistant, euthanasia technician, ambulatory surgical center,
facility for treatment with narcotics, researcher, instructional user or
any other authorized person to prescribe or possess controlled
substances80
For the biennial renewal of authorization of a physician, advanced
practice registered nurse, physician assistant, euthanasia technician,
ambulatory surgical center, facility for treatment with narcotics,
researcher, instructional user or any other authorized person to
prescribe or possess controlled substances

- 2. The penalty for failure to pay the renewal fee for any license, permit or certificate within the statutory period, as provided in subsection 6 of NRS 639.170, is 50 percent of the renewal fee for each period of delinquency in addition to the renewal fee for each period of delinquency.
- 3. Any person who has been registered as a pharmacist in this State for at least 50 years is not required to pay the fee for the biennial renewal of a certificate of registration as a registered pharmacist.
- 4. The provisions of this section concerning the fee for the biennial renewal of the authorization to dispense controlled substances or dangerous drugs do not apply to an advanced practice registered nurse who is required to pay a fee pursuant to NAC 639.870.
 - 5. A health center:
- (a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, that provides health care primarily to medically underserved persons in a community; and
 - (b) Which is not a medical facility as defined in NRS 449.0151,
- is not required to pay the fee for the collective certification of advanced practice registered nurses in the employ of a public or nonprofit agency as set forth in subsection 1.
 - 6. A practitioner employed by or serving as an independent contractor of a health center:

- (a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, that provides health care primarily to medically underserved persons in a community; and
 - (b) Which is not a medical facility as defined in NRS 449.0151,
- is not required to pay a fee to the Board for a change of address or for an additional address at which the practitioner dispenses drugs.
- 7. A practitioner who is exempt from the payment of a fee pursuant to subsection 6 shall notify the Board in writing of each change of address or additional address, or both.
- 8. In addition to any other fees paid by an applicant for a certificate, license or permit issued pursuant to chapter 639 of NRS, the Board may require that such an applicant, including, without limitation, a person who holds a certificate, license or permit in another jurisdiction, pay any costs of inspection incurred by the Board.